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EXAMINER	
HADDAD, MAHER M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,817	MANKELOW ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-34* is/are pending in the application.

4a) Of the above claim(s) *23,24 and 29-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 23-34 are pending.

2. Applicant's election of Group II (not Group I), claim 11 (now claims 25-34) drawn to an antagonist of a ligand for an epitope or footprint domain for binding integrins comprising a domain of ICAM-4 and the species of SEQ ID NO: 9, filed on9/6/07, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 23-24 (non-elected Group) and 29-34 (non-elected species) are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 25-28 are under examination as they read on an antagonist of a ligand for an epitope or footprint domain for binding integrins comprising a domain of ICAM-4 and the species of SEQ ID NO: 9.

5. Applicant's IDS, filed 5/3/05, is acknowledged.

6. The term "or more amino acid residues of said A, C, F, or G strands or said CE loop of ICAM-4" recited in claim 26, is objected to because the term does not further limit the subject matter of a previous claim, claim 25.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The recitation of "W66 on strand E of domain 1 of ICAM-4, ..., wherein said E strand (SEQ ID NO:5) is defined by amino acid residues 160 to 170 of ICAM-4" in claim 25, lines 8-10 is ambiguous because it is unclear how position W66 would be defined by residues 160-170 of the same ICAM-1 molecule. Further, it is noted that there is no Trp in SEQ ID NO: 5 or at positions 160-170.

B. The recitation "said epitope is further defined by" in claim 25, lines 7-8 is ambiguous because it is not clear which epitope is further defined, the term "epitope" has been recited in the claim at least 3 time before. It is not clear which epitope is further defined by amino acid residues W66 on strand E of domain 1 of ICAM-4.

C. The recitation "in which said antagonist or its active site" claimed in claim 28, lacks sufficient antecedent basis in base claim 27, base claim 27 only recite "antagonist".

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 28-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a peptide consisting of SEQ ID NOs: 9-11 as antagonists of ICAM-4, does not reasonably provide enablement for any antagonist of any ligand for the claimed epitope or claimed footprint domain for binding to any integrin or any antagonist of a functional homologue or the claimed epitope or an antagonist of any functional homologue of the claimed footprint domain in claim 25, in which said antagonist "has or consists essentially of" "three, four, five, six , seven, eight, nine or more amino acid residues of said A, C, F, or G strands or said CE loop of ICAM-4" or "a functional homologue thereof" in claim 26, or any antagonist defined by ICAM-4 strand A includes amino acid residues F18, W19 and V20 of ICAM-4 in claim 27 or in which said antagonist or "its active site" "has or consists essentially of" an amino acid sequence as defined in SEQ ID NO: 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation. Besides SEQ ID NOS: 9-11, the specification fails to provide any guidance as to how to use antagonist.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification on page 4, lines 20-21, page 5, lines 4-5, and lines 9-11 discloses that the antagonist may be an antibody, a compound, for example a low molecular weight compound, or a three, four, five, six, seven, eight, nice or more amino acids residues of A, C, F or G strands or the CE loop of ICAM-4. A person of skill in the art is not enabled to make and use any "antagonist" including antibody, low molecular weight compounds or 1-9 or more amino acid residues from the ICAM-4 strands that binds to the epitope stand to reduce adhesion between ICAM-4 and its ligands. It was well known in the art at the time the invention was made that molecules having highly diverse structural and biochemical properties can function as "antagonists". However, Huang (Pharmacol. Therapeutics 2000 86:201-215) reviews in his "Introduction" on page 202 the daunting task faced by the skilled artisan in developing small

molecule regulators of protein-protein interactions, and notes that the process required long periods of trial and error testing before suitable compounds could be developed. Further, it is recognized in the art that ligands must posses significant structural and chemical complementarity to their target receptors (Kuntz, Science, 1992, Vol. 257:1078-1082, especially page 10709, 2nd col., lines 1-4 and 9-12 under heading "Structure-Based Design) and that ligands generally bind to native states of proteins with little or no interaction with unfolded states (Miller et al, Protein Science, 1997, 6:2166-2179, especially page 2166, 2nd col., lines 18-20) and further that alterations in protein structure lead to alterations in bindings affinity proportional to the magnitude of the alteration (Miller et al, abstract, lines 2-4). Finally, Kuntz teaches that as little as 2% of compounds predicted to inhibit specific enzymztic or receptor systems actually shown inhibition in the micromolar range (page 1080, 3rd col.). The claims encompass alterations in antagonist folding because claims do permit deviation from the amino acid sequences of the consensus regions for a non-native peptide. It would be reasonable to conclude that alterations in peptide folding would lead to a large alteration in binding affinity. Thus in the absence of working examples or detailed guidance in the specification, the intended uses of any antagonist such as a simple or complex organic or inorganic molecule, a peptide or antibodies are fraught with uncertainties.

At issue further, the "functional homologues", the specification on page 4, lines 17-18 discloses that functional homologues or the epitope or footprint domain include mammalian homologues, for example mouse homologues. However, Spring et al (Blood, 98(2), 2000, IDS ref) teach that ICAM-4 is clearly an unusual molecule because it can be ligand for $\alpha 4\beta 1$, which has a preference for LDV-based sequences, and also for αv integrins that usually bind ligands containing the RGD sequence. Further, Spring et al teach that unlike other ICAMs, ICAM-4 domain 1 does not have the consensus $\alpha L\beta 2$-binding motif in the C strand. Unlike VCAM-1 and MAD-CAM-1, ICAM-4 also lacks a consensus $\alpha 4\beta 1$-binding motif in the C-D loop of this domain. IgSF molecules are highly versatile and can use almost any surface for ligand recognition (see page 465, last ¶ in particular). Applicant has not provided sufficient biochemical information (e.g. amino acid sequences, etc.) that distinctly identifies the functional homologue of epitopes or footprint domains other than those encompassed by set forth in SEQ ID NO:1. "It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992). The specification fails to provide functional homologue and species homologue of SEQ ID NO: 1. Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use of the claimed homologues in manner reasonably correlated with the scope of the claims broadly including any number of homologue of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement. The specification does not provide for sufficient enablement for homologues of SEQ ID NO: 1 other than those defined by SEQ ID NO: 1; which in turn, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

There does not appear to be sufficient guidance in the specification as filed as to how the skilled

artisan would make and use the various antagonist of a ligand for an epitope or footprint domain for binding integrins as claimed comprising FWV motif recited in the instant claims 27-28. The claimed SEQ ID NO: 9 sequence contain nine amino acid residues in length. It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different biological activities. Because of the lack of sufficient guidance and predictability in determining which modifications would lead to a peptide that exhibits specific binding inhibition to ICAM-4/ligand, and that the relationship between the peptide and its activity was not well understood. There is definite relationship between structure and function. Further, the terms "has" and "consists essentially of" are open-ended. They would open up the claimed antagonist or ICAM-4 stand A or SEQ ID NO:9 to include additional unidentified amino acid residues on either or both of the N- or C- termini of given sequence in large amounts. Further, the FWV motif in larger polypeptide molecule would not be for binding to ICAM-4 ligand. The skilled in the art would conclude that FWV motif buried a larger sequence would not be accessible for binding to ICAM-4 ligand.

While the specification on page 16 lines 18-20 discloses that due to the overlap of the αv integrin and α4β1 binding site with that of the binding site of LFA-1 and Mac-1, we predict that the peptides also inhibit any ICAM-4/LFA-1 or Mac-1 interaction. However, the specification on page 20, lines 17-20 discloses that inhibition of HEL cells (VLA-1) cell binding and HT1080 (αv) cell binding to human and murine ICAM-2Fc with SEQ ID NO: 9 and SEQ ID NO: 10 but not SEQ ID NO: 11. Further on page 22, lines 1-9 discloses that the F and the G strand peptides (SEQ ID NO:10 and 11, respectively) inhibit adhesion whereas the strand A and D (SEQ ID NOs: 9 and 13, respectively) peptides had no effect. This suggest, along with the data already provided of the peptide inhibition of HEL (VLA-4, α4β1) cell-ICAM-4 adhesion, that the area of interaction with α4β1 on ICAM-3 lies in the F and G strands of domain-1. Further, the specification on page 23, lines 12-14, discloses that neutrophil-ICAM-4 adhesion is mediated by β2 integrins (αLβ2 and αMβ2) and that it is likely to involve an interaction with the G and F strands of domain 1 of ICAM-4 as opposed to the A strand. Accordingly, the antagonist defined by ICAM-4 strand A, such as SEQ ID NO: 9 is not the magic bullet for inhibiting all the interaction between ICAM-4 and its ligands. The specific nature of this antagonist effect was confirmed by the specification. Accordingly, it cannot be seen how such peptide would be an antagonist for any ligand for binding any integrins as claimed in claim 25.

Finally, while claim 25 claims the antagonist of a ligand for a specific epitope or footprint domain of ICAM-4. The specification uses either human or murine ICAM-4Fc in the inhibition experiment. The specification fails to show that the cell inhibition via specific integrin only requires strands A and G of domain 1 of ICAM-4, for example, or the claimed strands or footprints as claimed in claim 25.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. Claims 25-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a peptide consisting of SEQ ID NOs: 9-11 as antagonists of ICAM-4.

Applicant is not in possession of any antagonist of any ligand for the claimed epitope or claimed footprint domain for binding to any integrin or any antagonist of a functional homologue or the claimed epitope or an antagonist of any functional homologue of the claimed footprint domain in claim 25, in which said antagonist "has or consists essentially of" "three, four, five, six , seven, eight, nine or more amino acid residues of said A, C, F, or G strands or said CE loop of ICAM-4" or "a functional homologue thereof" in claim 26, or any antagonist defined by ICAM-4 strand A includes amino acid residues F18, W19 and V20 of ICAM-4 in claim 27 or in which said antagonist or "its active site" "has or consists essentially of" an amino acid sequence as defined in SEQ ID NO: 9.

Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms, that are common to the genus. That is, the specification provides neither a representative number of species (antagonist) to describe the claimed genus, nor does it provide a description of structural features that are common to species (antagonist). The specification provides no structural description of antagonist other than ones specifically exemplified; in essence, the specification simply directs those skilled in the art to go figure out for themselves what the claimed antagonists looks like. The specification's disclosure is inadequate to describe the claimed genus of antagonists.

Applicant has disclosed only amino acid of SEQ ID NO: 9-11; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hermand et al (IDS ref. No. A03).

Hermand et al teach an antagonist (strand A, N-terminal peptide of ICAM-4-D1, i.e., ^{18}**F**^{19}**W**^{20}VRMSPEFV^{27} (as claimed in claim 27)) of a ligand (ICAM-4) for an epitope or footprint domain (D1-D2 domain) for binding LFA-1 integrin as claimed in claim 25 (see Fig. 1 in particular), in which epitope comprises the A strand of ICAM-4-D1 beginning at amino acid residues ^{18}**F**^{19}**W**^{20}VRMSPEFV^{27} and the G strand of ICAM-4-D1 ^{90}KTRWATSRITA^{100} (see Fig. 1A), wherein the antagonist "has or consists essentially of" 10 amino acid residues of said A strand as claimed in claim 26, in which said antagonist defined by ICAM-4 strand A includes amino acid residues F18, W19 and V20 of ICAM-1 as claimed in claim 27.

Furthermore, Hermand et al teach an antagonist (anti-LW mAbs BS46, BS56, and BS87 antibodies) of a ligand (ICAM-4) for an epitope or footprint domain (D1-domain) for binding LFA-1 integrin, in which epitope comprises the A strand of ICAM-4-D1 beginning at amino acid residues ^{18}**F**^{19}**W**^{20}VRMSPEFV^{27} and the G strand of ICAM-4-D1 ^{90}KTRWATSRITA^{100} (see Fig. 1A and page 26005, 2nd col. in particular). Herman et al further teach that the three mAbs bind the wild-type ICAM-4-Fc protein carrying the two Ig-like domains D1 and D2 as well as to the deletion mutant lacking domain D2 but did not bind the deletion mutant lacking domain D1 (page 26005, 2nd col. in particular). In addition, Herman et al teach that the three antibodies bind did not bind to mutant proteins comprising W19A substitution (see Table 1 and page 26006, 2nd col., in particular). Herman et al concludes that ICAM-4 binds to LFA-1 (CD11a) within Domain 1.

When a claim recites using an old composition or structure (e.g. strand A) and the use is directed to a result or property of that composition or structure (antagonist) then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The reference teachings anticipate the claimed invention.

14. Claims 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailly et al (IDS Ref No. A01) as is evidenced by the provisional Applicant No. 60/423,391 at page 1.

Bailly et al teach the N-terminal peptide sequence antagonist of the LW (ICAM-4) glycoprotein AQSPKGSPLASG(G)SV**PFXVRM(S)**(P) which has an amino acid sequence as defined in claimed SEQ ID NO: 9, wherein X is undetermined amino acid. The peptide has more amino acid residues of A strand as claimed in claim 26, in which said peptide defined by ICAM-4 strand A includes amino acid residues F18, W19 and V20 of ICAM, as claimed in claim 27 (see table 1). X being W is inherent property of the N-terminal peptide sequence of ICAM-4, as is evidenced by provisional Application No. 60/423,391 at page 1, that the amino acid X at position 18 is W in the mature human ICAM-4 sequence.

Claim 28 is included because the terms "has" and "consists essentially of" are open ended they would open up the sequence to included the extra amino acids on the N terminal and the one amino acid on the C-terminal.

The referenced N-terminal peptide sequence would act as antagonist of the ICAM-4 for an epitope or footprint domain for binding integrins. Further, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Also, as restated in the court in Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

The reference teachings anticipate the claimed invention.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 22, 2007

Maher Haddad

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